United States Senate

WASHINGTON, DC 20510

August 18, 2020

The Honorable Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We are examining the U.S. Food and Drug Administration's (FDA) efforts to provide potential treatments to patients suffering from COVID-19. Specifically, we write to request information regarding the FDA's decision to issue and then subsequently revoke the Emergency Use Authorization (EUA) to permit the use of hydroxychloroquine (HCQ) and chloroquine (CQ) to treat COVID-19 patients. Additionally, on August 10th, the FDA denied the EUA for outpatient use of HCQ by Henry Ford Health System physicians.[1]

On May 29th, you emphasized the importance of utilizing every possible treatment option to best address the needs of individual patients—including off-label prescribing of HCQ and CQ to treat or prevent COVID-19.[2] You stated that the FDA does not regulate the practice of medicine and that prescribing off-label medicines like HCQ and CQ to treat COVID-19 is based on an individual assessment for the patient.[3]

However, we have heard from licensed physicians that have had a far different experience with the FDA's approach. The physicians are concerned about the FDA's decision to revoke the March 28th EUA for HCQ and CQ for treatment of COVID-19. They have described the clear differences between inpatient and outpatient treatments and how this decision has affected their ability to treat patients in different settings. The physicians have warned that the FDA's EUA revocation of HCQ and CQ has led to misinformation and confusion across the country. Some states have restricted the ability of physicians to write and pharmacies to fill HCQ and CQ prescriptions under the longstanding and well-established authority to prescribe FDA approved drugs off-label with a patient's informed consent and according to their clinical judgement.[4]

The licensed physicians we have heard from have stressed the potential benefits of early outpatient treatment of HCQ for individuals infected with COVID-19. These physicians have pointed to the low mortality rates in other countries —like India, Turkey, South Korea, and Morocco— that are using HCQ widely on outpatient COVID-19 populations before the disease progresses to more lethal stages of the virus that require hospitalization.[5] However, the physicians are concerned that the FDA's actions regarding

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[1] Letter from Dr. Peter Stein, Dir., Office of New Drugs, U.S. Food & Drug Admin., to Dr. John McKinnon, Fellowship Research Coordinator, Dep't of Med., Henry Ford Hosp. (Aug. 10, 2020) (on file with Majority Staff, U.S. Senate Committee on Homeland Security and Governmental Affairs).

[2] Stephen M. Hahn, *Bringing a Cancer Doctor's Perspective to FDA's Response to the COVID-19 Pandemic*, FDA Voices (May 2020), https://www.fda.gov/news-events/fda-voices/bringing-cancer-doctors-perspective-fdas-response-covid-19-pandemic.

[3] *Id.*

[4] *State Action on Hydroxychloroquine and Chloroquine Access*, LUPUS FOUND. OF AM., https://www.lupus.org/advocate/state-action-on-hydroxychloroquine-and-chloroquine-access (last updated July 30, 2020). Following the FDA's revocation of the EUA for HCQ and CQ on June 15, 2020, Arkansas and Kansas updated state guidance regarding HCQ and CQ use for COVID-19. *Id.* Both states cited the FDA's revocation in their updated guidance, and Arkansas stated that based on the FDA's June 15 revocation, HCQ and CQ should be avoided in both outpatient and hospitalized settings as a treatment for COVID-19. *Id.*

[5] *Early Treatment with Hydroxychloroquine: A Country-Randomized Controlled Trial*, HCQ TRIALS (Aug. 5, 2020), https://hcqtrial.com/ (last updated Aug. 13, 2020).